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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/964,240	Applicant(s) Tanaka et al.
	Examiner Christopher Tate	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 19, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, and 13-16* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election without traverse of Group II, claims 3-12, in Paper No. 5 is acknowledged. Accordingly, claims 3-12 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming subject matter which the applicant regards as his invention.

Claims 4, 6 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 8 are rendered vague and indefinite by the phrase "wherein the vaccine or medicament comprises a nucleic acid vaccine or medicament". It is unclear by this phrase if the vaccine or medicament is composed of nucleic acid, is produced by a nucleic acid (e.g., a protein), or something else? In addition, it is somewhat unclear if the limitation "nucleic acid" applies to "medicament" as well as to "vaccine" or if it just applies to "vaccine".

Claim 6 is rendered vague and indefinite because it is unclear how the steps recited therein relate the method steps of claim 5 - e.g., are these steps further defining the preparatory method of claim 5 and, if so, why does the first step of claim 6 begin with step e) instead of step d) since claim 5 ends with step c)? In addition, the last two steps of claim 6 recite steps "e)" and "f)" following step h) which causes confusion as these final two steps could be construed as

alternative embodiments of the initial steps "e)" and "f)". It appears that claim 6 should actually depend from claim 3. It is therefore suggested that claim 6 depend from claim 3 and that the steps defined in claim 6 be recited in alphabetical order beginning with step a).

Claim 7 is rendered vague and indefinite by the two administration steps recited therein (steps a and b) - e.g., what is the temporal relationship of these steps: is the vaccine or medicament administered together (co-administered) or administered separately (and if so, is the pine cone extract administered, e.g., 1 minute, 1 day, 1 week, 1 year later) ?

Claim 9 is somewhat unclear because the preparatory steps recited therein begin with step d) - are steps a) - c) missing? - i.e., this gives the appearance that the extract preparation method of claim 9 is incomplete. It is suggested that steps d) - f) be amended to recite a) - c), respectively.

Claim 10 is rendered vague and indefinite because it depends from a non-elected claim (claim 2). It is suggested that claim 10 depend from claim 6.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3, 7, 11, and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Xin (CN 1279107 - DWPI Abstract).

A composition comprising a medicament and a pine cone extract is claimed, as well as a method of treating a vertebrae via administering the composition including to treat cancer or viral infections.

Xin teaches a medicine for treating AIDS and cancers which comprises castor (a medicament), phytolacca root extract (also a medicament), liquorice root extract (also a medicament) and pine cone extract which is disclosed as being administrable via injection or orally (slow release capsules). Since AIDS is an affliction of humans, the reference reads upon vertebrae treatment.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, 7, 8, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xin (CN 1279107) or Sakagami et al. (US 4,985,249), in view of Sham et al. (US 5,914,332).

The Xin reference is relied upon for the reasons discussed above.

Sakagami et al. teach anti-HIV, anti-tumor extract substances (which were effectively demonstrated *in vitro*) obtained from pine cones (termed KS-6 and KS-7: either of which also constitutes a medicament) - see entire document including claims. Sakagami et al. beneficially disclose it is highly probable that these extract substances might improve the condition of AIDS patients (due to their immunopotentiating activity) and their effect might be augmented by combinational treatment with other chemotherapeutic agents (see, e.g., col 4, line 52 - col 5, line 2). Neither Xin nor Sakagami et al. expressly teach incorporating such pine cone extracts within an anti-viral vaccine (such as an anti-HIV vaccine) or an anti-cancer vaccine.

Sham teaches an anti-HIV compound for administration to AIDS patients, whereby the compound may be administered in various pharmaceutical forms (e.g., orally, injectably) including incorporating a pharmaceutically acceptable adjuvant therein (see, e.g., col 72, line 65 - col 73, line 44). Sham also beneficially teaches that the compound can be administered in combination with a pine cone extract and/or with a vaccine such as one of various HIV vaccines (see, e.g., col 74, line 57 - col 75, line 67).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the pine cone extract agents taught by either Xin or Sakagami et al. with other anti-HIV or other anti-cancer agents including an HIV vaccine component based upon the beneficial teachings provided by Sham, and also because Sakagami et al. expressly disclose that their pine cone extract substances provide beneficial immunopotentiating activity. In addition, please note that it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (i.e., for treating HIV and/or cancer). The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The adjustment of particular conventional working conditions (e.g., selecting a particular type of conventionally

employed HIV vaccine, such as a nucleic acid HIV vaccine, for incorporation therein, and/or selecting a particular conventional means of administering such a composition, such as intramuscularly or via inhalation), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Christopher R. Tate
Primary Examiner, Group 1654